

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

Claims 1-7, 9-13, 16-34 are pending.

Claim 33 has been withdrawn.

Claims 1-7, 9-13, 16-32 and 34 are currently under examination.

35 USC § 112 rejections withdrawn

The rejections of claims 1-7, 9-13, 16-32 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement are withdrawn in view of Applicants arguments.

35 USC § 103(a) rejections withdrawn

The rejection of claims 1-7, 9-13, 16, 18,19, 21-22, 24-32 under 35 U.S.C. 103(a) as being unpatentable over Bednarski et al (US Patent Application Publication 20020197210, published December 26, 2002, cited previously) in view of Kitagawa et al (J Urol, 1998, 160:1540-1545, Text, 1-8 in cited previously) in further view of Zalipsky et al (US Patent No: 7,108,863, issued Sept 19, 2006, filed Mar 26, 2002) are withdrawn in view of Applicants' amendments to claim 1.

The rejections of claims 1 and 18-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bednarski et al (cited previously) in view of Kitagawa et al (cited previously) in further view of Cullis et al (US Patent No: 6,417,326, issued July 9, 2002, cited previously), and Zalipsky et al (US Patent No: 7,108,863, issued Sept 19,

2006, filed Mar 26, 2002, cited previously) are withdrawn in view of Applicants' amendments to claim 1.

The rejections of claims 1 and 14 -17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bednarski et al (, cited previously) in view of Kitagawa et al (cited previously) in further view of Slater et al (US Patent No: 6,355, 268, issued March 12, 2002, cited previously) and Zalipsky et al (US Patent No: 7,108,863, issued Sept 19, 2006, filed Mar 26, 2002, cited previously) are withdrawn in view of Applicants' amendments to claim 1.

NEW REJECTIONS: Based on the Amendment

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-7, 9-13, 16, 18,19, 21-22, 24-32 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bednarski et al (US Patent Application Publication 20020197210, published December 26, 2002, cited previously) in view of

Kitagawa et al (J Urol, 1998, 160:1540-1545, Text, 1-8, cited previously) in further view of Hansen et al (Biochim Biophysica Acta, 1995, 1239:133-144).

The claims are drawn to lipid membrane structure containing an anti-membrane-type matrix metalloproteinase monoclonal antibody (anti-MT-MMP), wherein the lipid membrane structure contains a substance for binding the anti-MT-MMP to the lipid membrane structure and a blood retentive lipid derivative, wherein the amount of the substance for binding the anti-MT-MMP to the lipid membrane structure is between 5 and 10 mol% based on the blood retentive lipid derivative in the lipid membrane structure, wherein the monoclonal antibody is present in a lipid membrane, on a surface of lipid membrane, in an internal space of lipid membrane, in a lipid layer, and/or on a surface of lipid layer of the lipid membrane structure, wherein the monoclonal antibody binds to a membrane surface of the lipid membrane structure, wherein the monoclonal antibody consists of one or more kinds of monoclonal antibodies selected from an anti-MT1-MMP monoclonal antibody, an anti-MT2-MMP monoclonal antibody, an anti-MT3-MMP monoclonal antibody, an anti-MT4-MMP monoclonal antibody, an anti-MT5-MMP monoclonal antibody, and an anti-MT6-MMP monoclonal antibody, wherein the monoclonal antibody is a human monoclonal antibody or a mouse monoclonal antibody, wherein the monoclonal antibody is a Fab fragment, a F(ab').sub.2 fragment, or a Fab' fragment, wherein the substance for binding the monoclonal antibody to the lipid membrane structure is a lipid derivative that can react with mercapto group in the anti-MT-MMP monoclonal antibody, which contains a phospholipid and/or a phospholipid derivative as a component of the lipid membrane structure, wherein the phospholipid and/or the phospholipid derivative consists of one or more kinds of phospholipids and/or phospholipid derivatives selected from the group consisting of phosphatidylethanolamine, phosphatidylcholine, phosphatidylserine, phosphatidylinositol, phosphatidylglycerol, cardiolipin, sphingomyelin, ceramide phosphorylethanolamine, ceramide phosphorylglycerol, ceramide phosphorylglycerol phosphate, 1,2-dimyristoyl-1,2-deoxyphosphatidylcholine, plasmalogen and phosphatidic acid, which further contains a sterol as a component of the lipid membrane structure, wherein the sterol is cholesterol and/or cholestanol, which contains a

temperature-sensitive lipid derivative as a component in the lipid membrane structure, which contains a pH-sensitive lipid derivative as a component of the lipid membrane structure, which reacts with a membrane-type matrix metalloproteinase on a tumor cell membrane, wherein the tumor cell is an MT-MMP expressing cell, wherein the tumor cell is a cell of fibrosarcoma, squamous carcinoma, neuroblastoma, breast carcinoma, gastric cancer, hepatoma, bladder cancer, thyroid tumor, urinary tract epithelial cancer, glioblastoma, acute myeloid leukemia, pancreatic duct cancer or prostate cancer, which reacts with a membrane-type matrix metalloproteinase of a neoplastic vessel, wherein the lipid membrane structure is in the form of micelle, emulsion, liposome or a mixture, which is in a form of dispersion in an aqueous solvent, a lyophilized form, a spray-dried form or a frozen form, a pharmaceutical composition comprising the lipid membrane structure according to claim 1 and a medicinally active ingredient and/or a gene, wherein the medicinally active ingredient and/or gene is present in a lipid membrane, on a surface of lipid membrane, in an internal space of lipid membrane, in a lipid layer and/or on a surface of lipid layer of the lipid membrane structure, wherein the pharmaceutical composition is in a form of a dispersion in an aqueous solvent, a lyophilized form, a spray-dried form, or a frozen form, wherein the blood retentive lipid comprises phosphatidylinositol.

Bednarski et al disclose a therapeutic agent comprising a lipid construct, a targeting entity and a therapeutic or treatment entity, (claim 1, paragraph 46) wherein the lipid construct is a liposome, (paragraphs 51-55) the targeting entity is an antibody including monoclonal antibodies and antibody fragments and other antibody-derived molecules which retain specific binding, such as Fab, F(ab')₂, Fv, and scFv derived from antibodies) (paragraph 76-83), which target entities such as the matrix metalloproteases. (claim 15). The therapeutic agent may be used to treat cancer (paragraph 91) The antibody may be attached to the lipid molecules of the liposome through disulfide bonds. (paragraphs 60). The liposome comprise phospholipids, including phosphatidylcholine and phosphatidylethanolamine (paragraph 51), cholesterol (paragraph 53) and stabilizing agents, such as polyethylene glycol, which increase the half-life of the liposome in the circulation. (paragraphs 65-68). The

phospholipids of the liposomes are temperature and pH sensitive. Bednarski also discloses therapeutic entities including doxorubicin or other chemotherapeutic agents. (paragraph 48) which may be encapsulated by the liposome or may be associated on the surface of the liposome (paragraph 46). The composition comprising the liposomes can also include other components such as a pharmaceutically acceptable excipients, such as water, saline, Ringer's solution, dextrose solution, mannitol, Hank's solution, and other aqueous physiologically balanced salt solutions. (paragraph 88).

Bednarski et al does not disclose a monoclonal antibody consists of one or more kinds of monoclonal antibodies selected from an anti-MT1-MMP monoclonal antibody, an anti-MT2-MMP monoclonal antibody, an anti-MT3-MMP monoclonal antibody, an anti-MT4-MMP monoclonal antibody, an anti-MT5-MMP monoclonal antibody, and an anti-MT6-MMP monoclonal antibody that that targets tumor cells including urinary tract epithelial cancer and reacts with membrane-type matrix metalloproteinase of a neoplastic vessel, wherein the tumor cell is a cell of fibrosarcoma, squamous carcinoma, neuroblastoma, breast carcinoma, gastric cancer, hepatoma, bladder cancer, thyroid tumor, urinary tract epithelial cancer, glioblastoma, acute myeloid leukemia, pancreatic duct cancer or prostate cancer, which reacts with a membrane-type matrix metalloproteinase of a neoplastic vessel

Kitagawa et al discloses an anti-MT1-MMP monoclonal antibody which bound MT1-MMP on tissue specimens of urothelial carcinoma cells. (page 4, 1st paragraph; page 5, 2nd paragraph, Figure 5). The tissue specimens would include neoplastic vessels.

One of ordinary skill in the art would apply Kitagawa et al's monoclonal antibody to MT1-MMP to Bednarski et al's therapeutic agent comprising an immunoliposome because Bednarski et al claims target entities such as the matrix metalloproteases which include the specie MT1-MMP. Furthermore Kitagawa et al disclose that MT1-MMP is expressed on carcinoma cells which would make MT1-MMP a suitable target for Bednarski et als' immunoliposome. It would have been prima facie obvious to combine Bednarski et al's therapeutic agent comprising an immunoliposome with

Kitagawa et al's monoclonal antibody to MT1-MMP to make an immunoliposome that recognized MT1-MMP to target urothelial carcinoma cells expressing MT1-MMP.

Further, neither Bednarski et al nor Kitagawa et al disclose that the amount of the substance for binding the anti-MT-MMP to the lipid membrane structure is between 0.5 and 20 mol% based on the blood retentive lipid derivative in the lipid membrane structure.

Hansen et al disclose a range of concentrations of the substance for binding the antibody to the lipid membrane structure, N-(4—(4"-maleimidiphenyl)butyryl)-MPB-PEphosphatidylethanolamine (MPB-PE) to optimize the coupling of the antibody to the liposome (Fig. 2A). The mol% of mPEG-DSPE in the liposome is 3.3 mol%. The mol % of MPB used in the coupling method are within the range of .1 to 1 mol%. Thus, the mol% ratios of MPB/mPEG-DSPE used in the coupling method fall within the 5 to 10% mol% of the present claims. One of ordinary skill in the art would have been motivated to apply Hansen et al's ratio of DSPE-PEG-mal to DSPE-PEG to Bednarski et al and Kitagawa et al's immunoliposome that recognized MT1-MMP to optimize the delivery of the immunoliposome to the target urothelial carcinoma cells. It would have been prima facie obvious to combine Bednarski et al and Kitagawa et al's immunoliposome to Hansen et al's ratio of MPB/mPEG-DSPE to optimize delivery of immunoliposomes that recognized MT1-MMP to maximize cytotoxicity towards urothelial carcinoma cells.

Applicants argue that a review of Bednarski reveals that Bednarski only appears to disclose the targeting entity being the matrix metalloproteases including MMP2 and MMP9 in claim 15. Applicants further argue that there does not appear to be any other disclosure in Bednarski relating to the matrix metalloproteases, including MMP2 and MMP9 other than claim 15. Applicants argue that Bednarski's disclosure includes disclosure of a vast number of entities, and there is no motivation to pick and choose the metalloproteases from the vast number of disclosed entities.

Applicants argue that Kitagawa is a research paper merely directed to examining the mRNA expression of MT-MMP's and the tissue immunolocalization of MT1-MMP in human urothelial carcinomas and that the research of Kitagawa merely concludes that it

is possible that MT1-MMP and MT2-MMP play an important role in the invasiveness of human urothelial carcinomas and become candidate tumor markers and targets for anticancer and gene therapeutics. Applicants argue that there is no disclosure in Kitigawa that provides enablement and/or written description of any real world use, such as a use having unexpected characteristics as disclosed by Applicants' unexpected advantages. Applicants argue that the lipid membrane structure of the present invention can simultaneously target tumor cells and neoplastic vessels, in which MT -MMP is expressed, and can deliver a medicinally active ingredient and/or a gene efficiently to both of them. Applicants argue that conventional lipid membrane structures target either tumor cells or neoplastic vessels. Applicants further argue that the lipid membrane structure that can simultaneously target both of tumor cells and neoplastic vessels was first achieved by the present invention. Applicants argue that in the lipid membrane structure of the present invention, a medicinally active ingredient and/or a gene can be delivered to a tumor tissue even in a small stage in which generation of neoplastic vessels is being started, thereby a therapeutic treatment can be attained. Applicants state that the present invention was achieved on the basis of these findings.

Applicants argue that there must be some teaching or suggestion in the prior art that would motivate somebody having ordinary skill in the art to pick and choose a certain species from a vast disclosure. Applicants further argue that there must be some teaching or suggestion in the prior art that would lead one having ordinary skill in the art to modify the selected species to arrive at Applicants' recited subject matter. Applicants argue that the prior art does not provide any reason why one having ordinary skill in the art would have chosen the matrix metalloproteases including MMP2 and MMP9 in claim 15 of Bednarski and the prior art does not provide any sufficient reason to modify such disclosure with anti-MT-MMP.

Applicants further argue that there must be some teaching or suggestion in the prior art that would lead to modify the selected species to arrive at Applicants' recited subject matter. Applicants argue that the prior art does not only provide no reason why one having ordinary skill in the art would have chosen the matrix metalloproteases

including MMP2 and MMP9 in claim 15 of Bednarski, but the prior art does not provide any sufficient reason to modify such disclosure with anti-MT-MMP in the lipid membrane structure recited by Applicants.

Applicants arguments have been considered but are not persuasive. In response to Applicants arguments that that there must be some teaching or suggestion the prior art that would motivate somebody having ordinary skill in the art to pick and choose a certain species from a vast disclosure, the immunoliposome of Bednarski et al in view of Kitagawa et al and Hansen et al is a combination of known elements. One of ordinary skill in the art could have combined the elements as claimed by known method and that in combination, each element merely performs the same function as it does separately. Furthermore, one of ordinary skill in the art would have recognized that the results of the combination were predictable. Therefore the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, absent unexpected results. Kitagawa et al discloses an anti-MT1-MMP monoclonal antibody which bound MT1-MMP on tissue specimens of urothelial carcinoma cells. The motivation for combining Bednarski et al with Kitagawa was to make an immunoliposome that could be used to target urothelial carcinoma cells.

In response to Applicants arguments that that the lipid membrane structure of the present invention can simultaneously target tumor cells and neoplastic vessels, the fact that Kitagawa et al discloses an anti-MT1-MMP monoclonal antibody which bound MT1-MMP on tissue specimens of urothelial carcinoma cells would provide the motivation to make an immunoliposome comprising the anti-MT1-MMP monoclonal antibody to target urothelial carcinoma cells.

In response to Applicants arguments that there is no disclosure in Kitagawa that provides enablement and/or written description of any real world use, there is no requirement for functional data to satisfy the 35 USC 112 requirement. Prior art is presumed to be operable/enabling MPEP 2121. Furthermore, MPEP 2121, part III states

A prior art reference provides an enabling disclosure and thus anticipates a claimed invention if the reference describes the claimed invention in sufficient detail to enable a person of ordinary skill in the art to carry out the claimed invention; "proof of efficacy is not required for a prior art reference to be enabling for purposes of anticipation." *Impax Labs. Inc. v. Aventis Pharm. Inc.*, 468 F.3d 1366, 1383, 81 USPQ2d 1001, 1013 (Fed. Cir. 2006). See also MPEP § 2122.

Applicants have not convincingly demonstrated that Kitigara et al's use of the anti-MT1-MMP monoclonal antibody which bound MT1-MMP on tissue specimens of urothelial carcinoma cells was not enabled. Furthermore, as disclosed by Bednarski and well known in the art it is routine in the art to make an immunoliposome comprising antibodies that bind tumor cells. One of ordinary skill in the art would have been motivated to make an immunoliposome comprising an anti-MT1-MMP antibody to target urothelial tumor cells based on Kitigara et al's finding of MT1-MMP expression on tissue specimens of urothelial carcinoma cells.

In response to Applicants arguments that the lipid membrane structure of the present invention, a medicinally active ingredient and/or a gene can be delivered to a tumor tissue even in a small stage in which generation of neoplastic vessels is being started, thereby a therapeutic treatment can be attained, Applicants have supplied no evidence that the claimed immunoliposome performs as stated above. Furthermore, as previously stated, the fact that Kitagawa et al discloses an anti-MT1-MMP monoclonal antibody which bound MT1-MMP on tissue specimens of urothelial carcinoma cells would provide the motivation to make an immunoliposome comprising the anti-MT1-MMP monoclonal antibody to target urothelial carcinoma cells. These immunoliposomes would inherently bind neoplastic vessels.

In response to Applicants arguments that the showing of unexpected results in their examples depicted in Tables 5-7 at page 47,50 and 51 of their originally filed application, respectively, overcame any prima facie case of obviousness, it is noted that the immunoliposomes encompassed by the claims, as presently amended, are not commensurate in scope with the optimized immunoliposomes described in the examples depicted in Tables 5-7, wherein the DSPE-PEG-mal/DSPE-PEG m/e% ratio is between 5 and 10%.

Claims 1-7, 9-13, 16, 18-32 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bednarski et al (US Patent Application Publication 20020197210, published December 26, 2002, cited previously) in view of Kitagawa et al (J Urol, 1998, 160:1540-1545, Text, 1-8, cited previously) and Hansen et al (Biochim Biophysica Acta, 1995, 1239:133-144, cited previously) in further view of Cullis et al (US Patent No: 6,417,326, issued July 9, 2002, cited previously),.

The claims are drawn to lipid membrane structure containing an anti-membrane-type matrix metalloproteinase monoclonal antibody (anti-MT-MMP), wherein the lipid membrane structure contains a substance for binding the anti-MT-MMP to the lipid membrane structure and a blood retentive lipid derivative, wherein the amount of the substance for binding the anti-MT-MMP to the lipid membrane structure is between 0.5 and 20 mol% based on the blood retentive lipid derivative in the lipid membrane structure, wherein the temperature-sensitive lipid derivative is dipalmitoylphosphatidylcholine, pH-sensitive lipid derivative is dioleoylphosphatidylethanolamine.

Bednarski et al, Kitagawa and Hansen et al have been described supra.

Neither Bednarski et al, Kitagawa nor Hansen et al disclose the phospholipids dipalmitoylphosphatidylcholine and dioleoylphosphatidylethanolamine.

Cullis et al disclose liposomes comprising dipalmitoylphosphatidylcholine (column 10, lines 39-40) and dioleoylphosphatidylethanolamine. (column 14 ,lines 61-65).

One of ordinary skill in the art would have been motivated to apply Cullis et al's disclosure of the phospholipids dipalmitoylphosphatidylcholine and dioleoylphosphatidylethanolamine to Bednarski et al, Kitagawa and Hansen et al's immunoliposome because Bednarski et al disclosed that the materials which may be utilized in preparing the liposomes include any of the materials known in the art suitable in liposome construction. (paragraph 53). Bednarski et al's also disclosed that such materials include lipids with head groups including phosphatidylcholine and

phosphatidylethanolamine. (Id). It would have been prima facie obvious to combine Bednarski et al, Kitagawa and Hansen et al's immunoliposome with Cullis et al's disclosure of the phospholipids dipalmitoylphosphatidylcholine and dioleoylphosphatidylethanolamine to make an immunoliposome including the phospholipids dipalmitoylphosphatidylcholine and dioleoylphosphatidylethanolamine which are lipids that include the head groups phosphatidylcholine and phosphatidylethanolamine, respectively.

Therefore the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, absent unexpected results.

Claims 1-7, 9-19, 21-22, 24-32 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bednarski et al (US Patent Application Publication 20020197210, published December 26, 2002, cited previously) in view of Kitagawa et al (J Urol, 1998, 160:1540-1545, Text, 1-8, cited previously) and Hansen et al (Biochim Biophysica Acta, 1995, 1239:133-144, cited previously) in further view of Slater et al (US Patent No: 6,355, 268, issued March 12, 2002, cited previously).

The claims are drawn to lipid membrane structure containing an anti-membrane-type matrix metalloproteinase monoclonal antibody (anti-MT-MMP), wherein the lipid membrane structure contains a substance for binding the anti-MT-MMP to the lipid membrane structure and a blood retentive lipid derivative, wherein the amount of the substance for binding the anti-MT-MMP to the lipid membrane structure is between 0.5 and 20 mol% based on the blood retentive lipid derivative in the lipid membrane structure, comprising a polyethylene glycol-lipid derivative consisting of one or more kinds of polyethylene glycol-lipid derivatives selected from the group consisting of N-{carbonyl-methoxypolyethylene glycol-2000}-1,2-dipalmitoyl-sn-glycero-3-phosphoethanolamine, N-{carbonyl-methoxypolyethylene glycol-5000}-1,2-dipalmitoyl-sn-glycero-3-phosphoethanolamine, N-{carbonyl-methoxypolyethylene glycol-750}-1,2-distearoyl-sn-glycero-3-phosphoethanolamine, N-{carbonyl-methoxypolyethylene glycol-

2000}-1,2-distearoyl-sn-glycero-3-phosphoethanolamine and N-(carbonyl-methoxypolyethylene glycol-5000)-1,2-distearoyl-sn-glycero-3-phosphoethanolamine.

Bednarski et al, Kitagawa et al and Hansen et al have been described supra.

Neither Bednarski et al, Kitagawa, nor Hansen et al disclose the polyethylene glycol-lipid derivatives selected from the group consisting of N-(carbonyl-methoxypolyethylene glycol-2000)-1,2-dipalmitoyl-sn-glycero-3-phosphoethanolamine, N-(carbonyl-methoxypolyethylene glycol-5000)-1,2-dipalmitoyl-sn-glycero-3-phosphoethanolamine, N-(carbonyl-methoxypolyethylene glycol-750)-1,2-distearoyl-sn-glycero-3-phosphoethanolamine, N-(carbonyl-methoxypolyethylene glycol-2000)-1,2-distearoyl-sn-glycero-3-phosphoethanolamine and N-(carbonyl-methoxypolyethylene glycol-5000)-1,2-distearoyl-sn-glycero-3-phosphoethanolamine.

Slater et al disclose liposomes comprising N-(carbonyl-methoxypolyethylene glycol 2000)-1,2-distearoyl-sn-glycero-3-phosphoethanolamine. (column 23, lines 14-18).

One of ordinary skill in the art would have been motivated to apply Slater et al's disclosure of the polyethylene glycol-lipid derivative, N-(carbonyl-methoxypolyethylene glycol 2000)-1,2-distearoyl-sn-glycero-3-phosphoethanolamine to Bednarski et al, Kitagawa and Hansen et al's immunoliposome because Bednarski et al disclosed that the materials which may be utilized in preparing the liposomes include any of the materials known in the art suitable in liposome construction and proposes polyethylene glycol as an exemplary stabilizing polymer (paragraph 68). It would have been prima facie obvious to combine Bednarski et al, Kitagawa and Hansen et al's immunoliposome with Slater et al's disclosure of the polyethylene glycol-lipid derivative, N-(carbonyl-methoxypolyethylene glycol 2000)-1,2-distearoyl-sn-glycero-3-phosphoethanolamine to make an immunoliposome including the stabilizing agent N-(carbonyl-methoxypolyethylene glycol 2000)-1,2-distearoyl-sn-glycero-3-phosphoethanolamine.

Therefore the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, absent unexpected results.

Summary

Claims 1-7, 9-13, 16-32 and 34 stand rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Halvorson whose telephone number is (571) 272-6539. The examiner can normally be reached on Monday through Friday from 8:30am to 5 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Misook Yu, can be reached at (571) 272-0839. The fax phone number for this Art Unit is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Mark Halvorson/
Examiner, Art Unit 1642